AstraZeneca

September 24, 2004

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: **Docket No. 2004N-0242**
Response to FDA Call for Comments
Institutional Review Boards; Registration Requirements

Dear Sir or Madam:

Reference is made to the July 6, 2004 Federal Register notice announcing the request for comments on the Proposed Rule: Institutional Review Boards; Registration Requirements. AstraZeneca has reviewed this Proposed Rule and our comments are attached.

This submission contains trade secrets and confidential commercial information exempt from public disclosure pursuant to exemption 4 of the Freedom of Information Act and FDA regulations, and the disclosure of which is prohibited by the Federal Food, Drug, and Cosmetic Act, the Trade Secrets Act, and other applicable law. Pursuant to FDA regulations, AstraZeneca is entitled to notice, an opportunity to object, and an opportunity to seek pre-release judicial review in the event that FDA determines that all or any part of this submission may be disclosed.

Please direct any questions or requests for additional information to me, or in my absence, to Tony E. Catka, Associate Director, USRA, Regulatory Project Management, at 302-885-9659.

Sincerely,

Gary M. Cooper

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Enclosure

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US Regulatory Affairs
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Proposed Rule
[Docket No. 2004N-0242] Institutional Review Boards; Registration Requirements

General Comments

Comment 1

The concept of IRB registration will allow for clearer identification of IRBs involved with FDA regulated clinical research studies, and so this proposal is supported on that basis with the following comments.

Comment 2

The proposed rule does not take into account non-local or commercial IRBs, and should be revised to do so.

Page Number	Section Number	Comment or proposed replacement text
4	Part II, Section A, Item #1, 4th paragraph	It is recommended that the proposal to require non-US IRBs to register be deleted from the proposed rule. This would create, in some circumstances, significant difficulties for clinical investigators and sponsors since local regulations and some non-US privacy laws would make it impossible to meet the registration requirement.
4	Part II, Section A, Item #2, 2nd paragraph	The restrictions on selection of the senior officer of the institution must be, may be too prohibitive. That is, if the senior member of the institution also happens to be on the IRB, this should not invalidate the registration. Moreover, if the senior person did fall into one of the prohibited categories, the IRB seems to be open to enforcement action by FDA. This requirement does not appear to be previously included in 21 CFR part 56, and is not germane to the stated goals of this proposed rule. It is therefore recommended that the proposed rule be changed to simply indicate that the name of the senior person of the institution that has oversight responsibilities for the activities associated with the IRB be identified.
5	Part II, Section A, Item #2, 6th paragraph	In response to solicitation by FDA of public comment on the perceived value of collecting information on the accreditation status of IRBs, AstraZeneca notes that accreditation is not part of any requirement under 21 CFR part 56 at this time and that asking for this information from an IRB upon registration could be both burdensome and confusing. Until such time that

Page Number	Section Number	Comment or proposed replacement text
		accreditation is required and a standard for accreditation has been decided, the request for accreditation status should not be part of the IRB registration process.
5	Part II, Section A, Item #2, 7th paragraph	It is recommended that the registration process where more questions are sought for HHS funded research be clearly described so that IRBs, uninvolved with HHS funded research, are not confused.
5	Part II, Section A, Item #4	It is recommended that the proposed rule address how the registration process should be documented by the IRB if it registers electronically. It is suggested that the FDA consider using an acknowledgment.
7	Part II, Section A, Item #6, 2nd paragraph	In response to the invitation for comment by FDA relative to how best to ensure that all sponsors and investigators involved in clinical investigations using human subjects use only registered IRBs to review and approve those clinical investigations, the following is offered. It is recommended that the form FDA 1572 be modified to indicate that the investigator agrees to use an IRB that is registered and complies with 21 CFR part 56. Technically the 1572 as currently rendered is adequate, but the aforementioned revision would reinforce the need to comply with the registration obligations. Regulatory sanctions for investigators not using a registered IRB should be the same as those currently utilized for breaches of investigator responsibilities.
13	Part 56.106 (e)	The answer to the question of how an IRB revises its registration information is at variance with the process described in the first paragraph of Section II, Part A, item 5, page 6. Specifically, page 6 describes how the IRB should notify FDA within 30 days if it begins to review new types of regulated products. On page 13, the items requiring revision other than on the 3-year anniversary, were changes to contact information and if the IRB discontinues. The procedure should be revised to be clear and consistent.